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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,965	02/18/2004	Coni F. Rosati	27542-501 UTIL	4452

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MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
666 THIRD AVENUE
NEW YORK, NY 10017

EXAMINER

HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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101 781 965

EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

auaurall

Office Action Summary	Application No. 10/781,965	Applicant(s) ROSATI, CONI F.	
	Examiner Laura C. Hill	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-103 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 58-103 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/13/04 ; 4/15/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Tissue Dressing with Gas Reservoir for Improved Wound Healing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 58-59, 62-63, 66-68, 70-71, 74, 78-80, 86, 93, 96-97, 99 and 102-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Ladin (US 5,792,090; herein 'Ladin'). Regarding claims 58 and 86 Ladin discloses a wound dressing that produces a useful level of oxygen to produce a hyperoxic condition (col. 4, ll. 14-18), comprising an oxygen impermeable film wrap/top layer 101, 201 sealed to oxygen permeable membrane/bottom layer 104, 204 via periphery adhesive to form a gas containing reservoir 105 (col. 8, ll.18-64, figures 1, 2a and 2b).

Regarding claims 59 and 78-80 Ladin discloses assembly is held to the body surface by adhesive tape/backing 106, 206 (col. 8, ll. 27-28) that covers the perimeter of the bottom layer 104, 204 and is integrated with the entire wound dressing apparatus (figures 1, 2a and 2b).

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Regarding claims 62-63, 66-68 Ladin discloses the oxygen impermeable film wrap/top layer 101, 201 comprises polyvinylidene chloride laminate such as Saran®, polyamide (including any polyamide laminate trademarks), or polyethylene (col. 8, ll. 30-35, col. 11, ll. 1-6).

Regarding claims 70-71 Ladin discloses suitable bottom layers include microporous polymer film membranes having high permeability to gases include low-density polyethylene (col. 5, ll. 30-37).

Regarding claim 93 Ladin discloses raised projections/spaced apart ribs 303 on the top layer 301 (col. 9, ll. 5-10, figure 3b).

Regarding claims 96-97 Ladin discloses press-on cap/reinforced gasket 203 that seals top and bottom layers 201, 204 and extends into reservoir 205 (figures 2a and 2b).

Regarding claims 74 and 99 Ladin discloses two or more membranes having different adsorption and gas transmissive abilities may be used either as physically separate membranes/additional gas containing container, or as a laminate since the wound dressing contains both gaseous oxygen as well as dissolved oxygen (col. 5, ll. 15-22).

Regarding claim 102 Ladin discloses to counteract any tendency for the dressing, during oxygen generating quiescent periods to create excessive hypoxia/predetermined ratios, a minor amount of a continuous, low level, external oxygen generating source may be included in the dressing (col. 7, ll. 20-25).

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Regarding claim 103 Ladin discloses the top layer contains raised projections/ribs 303 that are convex when placed over the wound cavity (figures 2c and 3a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 60 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin') ~~as applied to claim 58 above, and further~~ in view of Benecke et al. (US 5,008,110; herein 'Benecke'). Ladin *does not expressly disclose* the top layer comprises a metallized polyester or EVOH. **Benecke** discloses a transdermal delivery device 10 with reservoir 16 sandwiched between upper and lower gas barrier films (col. 5, ll. 12-18, col. 7, ll. 17-22, figures 2-3). Benecke further discloses suitable materials for upper and lower gas barrier films include metallized polyester (col. 7, ll. 22-31), polyvinylidene chloride copolymer such as Saran®, EVOH laminate

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(including any brand of EVOH laminates) and other materials substantially impermeable to water vapor and oxygen (col. 7, ll. 1-16). One would be motivated to modify the top layer of Ladin with the metallized polyester and EVOH laminate of Benecke to provide a gas impermeable top layer since both layers are in the same field of endeavor; laminate wound dressings with oxygen impermeable layers. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the top layer, thus providing a top layer comprised of the aforementioned materials.

4. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin') as applied to claim 58 above, and further in view of Peiffer et al. (US 6,565,936; herein 'Peiffer'). Ladin *does not expressly disclose* the top layer comprises ceramically coated polyester. **Peiffer** discloses a film laminate with ceramically coated polyester film with improved oxygen barrier properties for use in food packaging (col. 1, ll. 45-46, col. 2, ll. 3-15). One would be motivated to modify the top layer of Ladin with the ceramically coated polyester of Peiffer since both references are in the same problem-solving area; multi-layered laminates for preventing oxygen permeation in selected layers. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the top layer, thus providing a top layer comprised of ceramically coated polyester.

5. Claims 69, 72-73 and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin') as applied to claim 58 above, and further in view of Sun et al. (US 6,465,709; herein 'Sun').

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Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Regarding claim 69 Ladin *does not expressly disclose* a heat-conducting top layer. **Sun** discloses a multi-layer exothermic bandage 500 consisting of a heat-generating layer 140 that serves as a means of controlling the oxygen availability and heat-insulating layer 160 adjacent the target area for enhanced topical and transdermal delivery of active agents and wound healing (col. 7, ll. 19-31, col. 1, ll. 7-9, col. 6, ll. 39-41, figure 1). One would be motivated to modify the top layer of Ladin with the heat conducting layers of Sun to provide enhanced active agents during healing since both references are in the same problem solving areas; multi-layer topical bandages for wound healing. Therefore, it would be obvious to one of ordinary skill in the art at the

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time the invention was made to modify the top layer, thus providing a heat-conducting top layer.

Regarding claims 72-73 and 89-90 Ladin discloses suitable bottom layers include microporous polymer film membranes having high permeability to gases as discussed above with respect to claim 71. Ladin *does not expressly disclose* the bottom layer allows non-gas entities such as nutritional or therapeutic agents to pass through. **Sun** discloses active agent-containing/bottom layer (the layer contains a reservoir or space for nutrients) 120 comprises a gauze, non-woven or sponge material containing nutrients and other biologically active agents/non-gas entities for treatment (col. 4, ll. 62-66, col. 5, ll. 1-4, figure 1). One would be motivated to modify the porous bottom layer of Ladin with the non-gas nutrient entities of Sun to enhance treatment since both references are in the same problem solving areas; multi-layer topical bandages for wound healing. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the bottom layer, thus providing non-gas entities such as nutritional or therapeutic agents to pass through.

6. Claims 75-77, 81-85, 98 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin') as applied to claim 58 above, and further in view of Cantwell (US 6,000,403; herein 'Cantwell'). Regarding claims 75-77, 81-85 and 100 Ladin *does not expressly disclose* a ring-shaped absorbent layer.

Cantwell discloses a topical hyperbaric bandage 1 with gas impermeable flexible material/top layer 2, gas/liquid-impermeable reservoir material/bottom layer 5 containing a therapeutic oxygen such as hydrogen peroxide and a ring-shaped

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humectants/moisture absorbing layer 7 between bottom layer 5, top layer 2 and target area for absorbing any residual water (col. 3, ll. 24-28 and 41-43, col. 4, ll. 32-39, figures 1-2). One would be motivated to modify the wound dressing of Ladin with the ring-shaped absorbent layer of Cantwell to absorb any residual liquid in the wound since both references are in the same problem-solving area; topical bandages with applied gas for improved healing. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the wound dressing, thus providing an additional absorbent layer.

Regarding claim 98 Ladin *does not expressly disclose* a septum. **Cantwell** discloses the hyperbaric bandage may comprise a biologically acceptable means for a support of a reducing metal, physically separated from the store (col. 2, ll. 12-15).

7. Claims 87-88 and 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin'). Regarding claims 87-88 Ladin *does not expressly disclose* the gas contained in the reservoir 105 is nitrogen or carbon dioxide. One would be motivated to modify the gas contained in the reservoir to include any type of gas acceptable to promote wound healing. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the gas contained in the reservoir, thus providing nitrogen and/or carbon dioxide in the reservoir.

Regarding claims 94-95 Ladin *does not expressly disclose* the wound dressing is in the form of a glove, mitten or sock. One would be motivated to modify the wound dressing of Ladin to include the aforementioned forms to provide wound healing on all areas of the body since Ladin discloses a structure that covers a portion of the body in a

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similar manner that a glove, mitten or sock cover a portion of the body. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the wound dressing, thus providing a wound covering in the form of a glove, mitten or sock.

8. Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin') as applied to claim 58 above, and further in view of Sun et al. (US 6,465,709; herein 'Sun'), and further in view of Hiles (US 5,762,678; herein 'Hiles'). Ladin/Sun *do not expressly disclose* the biologically beneficial agent 120 is contained in microcapsules. **Hiles** discloses in the art, it is known to utilize slow-release synthetic systems, which generally consists of nutrients encapsulated in a soluble or biodegradable polymer (col. 1, ll. 52-54). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the biologically beneficial agent of Ladin/Sun, thus providing a micro-capsulated agent.

9. Claims 92 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090; herein 'Ladin') as applied to claim 58 above, and further in view of Sun et al. (US 6,465,709; herein 'Sun'), and further in view of Kydonieus (US 4,764,382; herein 'Kydonieus'). Ladin/Sun *do not expressly disclose* the biologically beneficial agent 120 is contained in a gel matrix. Kydonieus discloses in recent years, various drug delivery systems have been developed which provide substantial release of a drug, such as transdermal drug delivery systems. These systems have taken various forms. Thus, for example, it is known in the art to incorporate a drug in a gel by a batch technique (col. 1, ll. 16-21). Therefore, it would be obvious to one of ordinary

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skill in the art at the time the invention was made to modify the biologically beneficial agent/drug, thus providing a drug contained in a gel matrix.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ewall (US 5,556,375) is cited for showing an island wound dressing with gas permeable cover sheet 13, absorbent pad 12 that fits in fenestration/hole 11, and gas barrier base layer 10. Eckert et al. (US 5,487,889) is cited for showing a biological bandage 10 for wound healing with gas permeable polysulfone, polypropylene, or polyethylene top membrane 14, and porous absorbent insert contained within spacer 48.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAIEVA
SUPERVISORY PRIMARY EXAMINER

